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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Common/Usual Name: Topical Hemostat

Product Trade Name: D-Stat Dry Hemostatic Bandage
D-Stat Radial Hemostatic Band
D-Stat 2 Dry Hemostatic Bandage

Classification Name: Unclassified
Product Code FRO

Manufacturer: Vascular Solutions, Inc.
2495 Xenium Lane North
Minneapolis, Minnesota 55441

Establishment Registration: 2134812

Contact: Gregory W. Sachs
Director of Regulatory Affairs

Performance Standards: No performance standards have been developed under section 514 for this device.

Device Description:

The D-Stat Dry Family Products consists of the following components:

- Lyophilized pad consisting of thrombin, sodium carboxymethylcellulose and calcium chloride
- Adhesive bandage

These Products achieve their principal intended action (hemostasis) by creating a physical barrier to blood flow with compression. The lyophilized components (thrombin, CMC, and calcium chloride) establish an environment, in which a natural blood clot can build and form a physical barrier to bleeding. The thrombin facilitates hemostasis by enhancing the surface-activated clotting cascade through enzymatic cleavage and conversion of fibrinogen to fibrin.

Intended Use:

The Vascular Solutions D-Stat Dry Hemostatic Bandage, the D-Stat Radial Hemostatic Band and the D-Stat 2 Dry Hemostatic Bandage, is intended for use under the direction of a healthcare professional for the local management and control of bleeding from vascular access sites and percutaneous catheters and tubes.

Summary of Non-Clinical Testing:

No additional non-clinical testing of this product for this use was conducted.

Summary of Clinical Testing:

No clinical evaluations of this product for this use have been conducted.

Predicate Devices:

Predicate devices are the Vascular Solutions D-Stat Dry Product Family: D-Stat Dry Hemostatic Bandage, the D-Stat Radial Hemostatic Band and the D-Stat 2 Dry Hemostatic Bandage.

Conclusions:

The D-Stat Dry Family Products, as noted above, 12-month testing results are acceptable, within product specification and substantiate an extension in product shelf life to 12 months.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 12 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Gregory W. Sachs
Director of Regulatory Affairs
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K040118
Trade/Device Name: Vascular Solutions D-Stat Dry Hemostatic Bandage,
D-Stat Radial Hemostatic Band, D-Stat 2 Dry Hemostatic Bandage
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 16, 2004
Received: January 20, 2004

Dear Mr. Sachs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Gregory W. Sachs

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040116

Device Name: Vascular Solutions D-Stat Dry™ Product Family [the D-Stat Dry Hemostatic Bandage, D-Stat Radial Hemostatic Band (K030836) and the D-Stat 2 Dry Hemostatic Bandage (K033709)]

Indications For Use:

.... is intended for use under the direction of a healthcare professional for the local management and control of bleeding from vascular access sites and percutaneous catheters and tubes.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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